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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,809	03/30/2004	Jeffrey Hutterer		6034

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,809	HUTTERER, JEFFREY	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,12-20 and 26-42* is/are pending in the application.

4a) Of the above claim(s) *36-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12-20,26-35,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of May 12, 2008 made to the office action filed December 12, 2007. Claims 1-6, 12-20 and 26-42 are pending. Claim 1 is amended and claims 40-42 are new. In a restriction filed October 31, 2007, Applicant elected claims 1-35, in which claims 36-39 were withdrawn. The new claim, 40 is also withdrawn because it is dependent on claim 37.

The Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 1-6, 12-20 and 26-35 have been considered and were found persuasive. Particularly, the Glasser reference does require that the antihistamine be administered with a diuretic and that the antihistamine was found virtually ineffective alone. Thus, the rejection is withdrawn and the new 35 U.S.C. 103(a) rejection is made below. Therefore, a new Non-Final rejection is made below.

In regards to the unexpected results, the Examiner does not find that the invention provides unexpected results over the new prior art. The combinations as taught by Roberts et al. in view of Pratt, McCadden, and O'Kane teach a fast treatment of dermatitis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 12-20, 26-35 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. (US 5,750,141), in view of Platt (WO 98/10647 A1), in view of McCadden (US 6,479,058 B1), in view of O'Kane et al. (The Physican and sports medicine, September 1999, vol. 27(9), pp. 1-14) in further view of Healthchemist (online pharmacy printout or Naphcon being sold).

Roberts et al. teach a method of topical and/or transdermal administration of a vaso-active agent administered in combination with a therapeutic agent which is useful in treatment of the dermis epidermis, wherein the therapeutic agent may be administered in a similar manner in combination with the vaso-active agent or may be administered separately so as to increase local perfusion and/or concentration of the therapeutic agent at the administration site of the vaso-active agent (see abstract and claim 1; addresses claims 1 and 27). The composition may also include a suitable vehicle or carrier (see column 6, lines 35-36). Therapeutic agents include

corticosteroids such as hydrocortisone and descamethasone, and antihistamines. (see column 6, lines 39, 40, 49, 53, 54 and 55; see column 6, line 52; addresses 1, 6, 20, 27, 29-34). Suitable vasoconstrictors include naphazoline (i.e. decongestant) and phenylephrine hydrochloride (i.e. decongestant; see column 7, lines 33, 41, 42 and 43; addresses claims 1, 3-5, 14-19 and 27).

Roberts et al. does not teach pheniramine maleate or the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27 and 28), or the amounts of the corticosteroid cream (claims 13 and 27), specifically a 1% cream of hydrocortisone (claims 12, 26 and 35).

Pratt teaches a topical preparation of an antihistaminic chemical compound and at least one hydrocortisone compound to treat various types of dermatitis (see abstract and title). The antihistamine can be pheniramine maleate (see page 7, line 19; claim 3). The combination effectively treats dermatitis caused by a noxious agent or by an allergic reaction much quicker and with deep penetration and time release features making it more effective than either over-the-counter or prescription preparations (see page 6, second paragraph in its entirety.)

McCadden teach a composition for the topical treatment of skin eruptions from psoriasis (see title and column 1, lines 19 and 20) comprising a corticosteroid of appropriate potency for the condition being treated (see column 2, lines 50-53) in the

form of a cream (see column 2, last line). Low potency steroids are generally preferred in view of certain disadvantages of high potency steroids such as hydrocortisone, most preferably from about 0.5 to about 2.5% (see column 4, lines 63-65 and column 5, lines 8-10). The composition is applied topically to the involved area until it has healed (see column 10, lines 11-12).

O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and pheniramine maleate, also known as Naphcon-A (see page 5, table 2, see page 6, topical vasconstrictors, third entry).

Healthchemist teaches that the Naphcon-A product comprisings 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active ingredients).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. and the combination of pheniramine maleate with either naphazoline HCl or phenylephrine HCl because of the following teachings: (1) Pratt teaches a topical preparation of an antihistaminic chemical compound and at least one hydrocortisone compound to treat various types of dermatitis (see abstract and title).; (2) Pratt teaches that the combination effectively treats dermatitis caused by a noxious agent or by an

allergic reaction much quicker and with deep penetration and time release features making it more effective than either over-the-counter or prescription preparations (see page 6, second paragraph in its entirety); and (3) "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Platt and the specific 1% cream of hydrocortisone (claims 12, 26 and 35) because McCadden teach a composition for the topical treatment of skin eruptions from psoriasis (see title and column 1, lines 19 and 20) comprising from about 0.5 to about 2.5% of the hydrocortisone cream (see column 2, lines 50-53; column 2, last line; column 4, lines 63-65 and column 5, lines 8-10). Thus, psoriasis is effectively treated with a 1% hydrocortisone cream. Therefore, one would be motivated to use this concentration of hydrocortisone for the method of Roberts et al. in view of Platt.

In regards to the actual amount of cream applied as disclosed in applicant's claims 13 and 27, it would be obvious to apply approximately 0.05 grams to approximately 0.2 grams because McCadden teaches that the hydrocortisone composition is applied topically to the involved area until it has healed (see column 10, lines 11-12). Thus, the amount to cover the area can comprise approximately 0.05 grams to approximately 0.2 grams, depending on the size of the area to be treated.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method steps and composition of Roberts et al. in view of Platt and the amounts of the combination solution (claims 1, 2, 3, 4, 5, 13-19, 27 and 28) because of the following teachings: (1) O'Kane et al. teach topical vasoconstrictors for the treatment of allergic conjunctivitis including the application of 1 drop of a 0.1% solution of Naphazoline HCl and pheniramine maleate, also known as Naphcon-A (see page 5, table 2, see page 6, topical vasconstrictors, third entry); (2) Healthchemist teaches that the Naphcon-A product comprisings 0.25 mg/ml of naphazoline hydrochloride and 3 mg/ml of pheniramine maleate (see active ingredients); and (3) It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994);

In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003). Thus, a combination of a decongestant and an antihistamine is known in the applicant's disclosed ratios and applied in the amounts of a volume of at least approximately 0.02 ml (1 to 2 drops). One skilled in the art can determine the amount needed to treat the affected area.

In regards to the method relieving or alleviating symptoms within approximately two to four minutes, or that the symptoms last for approximately two to five hours, the Examiner renders the above limitations obvious over the above references. Roberts et al. teach a method useful in treatment of the dermis epidermis in which the method can be adopted to prolonged periods of 2-12 hours (see column 7, lines 9-10). Since all references teach a method of treatment, it is viewed by the Examiner that the symptoms of the dermatitis is relieved or/and alleviated. In regards to the time factor, both Roberts et al. and Pratt describe that the methods used increase the effectiveness time by increasing penetration. Thus, one skilled in the art would anticipate that the combination would produce shorter relief times than the drugs individually as stated by Pratt (see page 6, second paragraph in its entirety.) Additionally, the combination as taught by Roberts et al. in view of Pratt would

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

/SREENI PADMANABHAN/
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